

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re Bair Hugger Forced Air Warming Devices Products Liability Litigation	MDL No. 15-2666 (JNE/DTS)
This Document Relates To: ALL ACTIONS	PLAINTIFFS' RESPONSE TO 3M'S OBJECTIONS TO THE LANGE, SUGAI, AND SOUSA ARTICLES

INTRODUCTION

3M asks the Court to disregard the Lange, Sugai, and Sousa articles for two reasons. First, says 3M, the articles are inadmissible hearsay because “[n]one of Plaintiffs’ experts cited any of the three articles in their reports.” Dkt. 1973 at 2. Second, says 3M, the articles are “irrelevant” to Plaintiffs’ theories of general causation. *Id.* 3M is wrong on both counts.

ARGUMENT

I. PLAINTIFFS’ EXPERTS DID NOT CITE THE STUDIES BECAUSE THEY COULD NOT SUPPLEMENT THEIR GENERAL CAUSATION REPORTS

3M’s hearsay argument fails for a simple reason: Plaintiffs’ experts could not have supplemented their general-causation reports to include the Lange, Sugai, or Sousa studies.

As previously explained, Dkt. 1914 at 20–21, Plaintiffs did not file supplemental reports given the Court’s Order striking Dr. David’s and Dr. Bushnell’s supplemental reports on general causation, Dkt. 1580 at 2, as well as the Court’s Order denying Plaintiffs’ request to conduct discovery on the Jeans study and to supplement their expert reports.

Dkt. 1781 at 1. Although Plaintiffs submitted an affidavit from Dr. Samet addressing the impact, if any, of Jeans's MSSA study on McGovern, Dkt. 1905 at 2, Lange and Sugai do not involve MSSA screening. Lange shows that internal contamination of forced-air warming devices increases risk of infection, while Sugai shows that these devices "have been shown to produce an unintended consequence of disrupting operating room airflow and contaminating the surgical field." (Lange was also published in June 2019, *after* Plaintiffs submitted general-causation reports and affidavits, opposed 3M's motion for reconsideration, and responded to the Court's three questions.) Sousa, on the other hand, addresses the impact of MSSA screening on DJI. But Plaintiffs' experts had no reason to cite that study in their reports because 3M did not rely on Jeans until August 2018, when it sought leave to move for reconsideration. Dkt. 1428 at 1. 3M's hearsay argument thus fails.

If the Court nonetheless excludes Lange, Sugai, or Sousa as inadmissible hearsay, that ruling should apply with even greater force to 3M's reliance on the 2018 International Consensus Statement (2018 ICOS). *See* Dkt. 1719 at 33–34; *see also* Dkt. 1849 at 18–20. Like the foregoing studies, none of 3M's experts cited the 2018 ICOS in their general-causation or specific-causation reports. But unlike Plaintiffs' experts, who were precluded from supplementing their reports in light of the Court's Orders, 3M could have done so given Dr. Borak's recent reliance on Jeans. *See* Dkt. 1719 at 30 (citing Borak's Rpt. ¶21). Accordingly, 3M's request to exclude the Lange, Sugai, and Sousa articles as inadmissible hearsay only highlights the weakness of its motion for reconsideration of general causation, separate and apart from its [REDACTED] the 2018 ICM as well as its

failure to understand the obvious distinction between “definitive” and “relevant” evidence of general causation. *E.g.*, Dkt. 1804 [REDACTED]

II. THE STUDIES ARE RELEVANT EVIDENCE OF GENERAL CAUSATION

Forecasting its failure to exclude Lange, Sugai, and Sousa on hearsay grounds, 3M alternatively—albeit equally unpersuasively—says the articles “do not help Plaintiffs because they are irrelevant to the causation questions before the Court.” *See* Dkt. 1973 at 1. Like its motion for reconsideration, 3M misunderstands the meaning of “relevance.” Plaintiffs address each of 3M’s challenges to each of these published studies *ad seriatim*.

A. The Lange Study Is Relevant Scientific Evidence of Plaintiffs’ “Second” Theory of General Causation Regarding Internal Contamination

3M raises three attacks on the Lange study. *First*, 3M insinuates that the study holds little weight because it is nothing more than a “short abstract,” ignoring the critical fact that 3M has told the public for decades that Hall’s two-page poster presentation proves the safety of Bair Hugger. Nor does 3M address—let alone acknowledge—that the *American Journal of Infection Control* published Lange’s study in its June 2019 Supplement, whereas Hall’s two-page poster presentation has never been reviewed or published in *any* journal.

Second, 3M’s attempt to distinguish Lange as involving other types of “FAW devices” rather than Bair Hugger is nonsensical. Unlike other FAW devices—including the Stryker Mistral cited in 3M’s papers—Bair Hugger does not use HEPA filtration. Instead of using HEPA filtration as it led the FDA to believe, [REDACTED]

[REDACTED].
[REDACTED].
See, e.g., Dkt. 311 at 13 (citing 3MBH00047382). Therefore, assuming for the sake of

argument that none of Lange's 35 FAW devices included Bair Hugger per 3M's rank speculation, the study results would have been worse—not better—with Bair Hugger.

Third, 3M claims that “sampling was not done at the business end of the Bair Hugger—the perforated blanket.” This is wrong. To be sure, Lange collected “surface samples” from “the internal hose surface, the proximal hose end, and the distal hose end.” However, he also collected “air samples” to determine the connection between “surface-component contamination and tissue-air risk connection.” Based on the internal and external sampling of “35 unique FAW devices,” Lange “identified a correlation of positive *airborne samples* for instances that had high-pathogen contamination in the warmer-temperature components, resulting in a possible *increased patient infection risk* and possible attributable SSI as primary concerns.” Once again, 3M simply ignores the key text and the bevy of evidence supporting Plaintiffs' internal contamination theory of causation.

B. The Sugai Study Is Relevant Scientific Evidence of Plaintiffs' “First” Theory of General Causation Regarding Airflow Disruption

3M also challenges the Sugai study on three grounds. *First*, like the Lange study, 3M contends that Sugai is irrelevant because “it does not study the Bair Hugger system.” But like Lange, 3M's argument does not hold water because Sugai's recommendations apply to all “forced-air warming (FAW)” devices, as that term is defined on the first page of the study. Indeed, Sugai never circumscribed its recommendation to “find an effective alternative to FAW” to certain FAW devices. Nor does it exclude Bair Hugger—the most popular FAW device—from its finding that “FAW systems have been shown to produce an unintended consequence of disrupting operating room airflow and contaminating the

surgical field.” After all, in warning that “*nothing* that blows air should be in an operating theater,” the CDC never drew a line between Bair Hugger and other devices. *See* Dkt. 1813-47 at 3. It broadly remarked that *no device should blow air* in the operating room. *See id.*

Second, 3M states that Sugai contains “obvious false statements” that the “CDC has issued a warning that nothing that blows air should be in an operating theatre.” Once again, 3M ignores the plain language of the CDC’s Record of Proceedings, which Sugai correctly recites as stating “nothing that blows air should be in an operating theater.” Worse, 3M refuses to recognize its own expert testimony that the CDC’s warning “*coincides with a lot of the concern*” regarding Bair Hugger. *See* Dkt. 807-7 at 94 (Holford Dep. at 371:3-372:3).

Third, 3M falls back on the unusual argument that Sugai’s “statements about the CDC are dicta.” Not so. In addition to emphasizing the CDC’s warning in the “discussion” section of the study, Sugai et al. predicated their recommendation to “find an effective alternative to FAW” on the same warning that “[n]othing that blows air should be in an operating theater.” The warning thus appears not just once but twice, highlighting its importance to Sugai’s finding that FAW has a “very high failure rate” despite its risks of “contaminating the surgical field.” All of 3M’s attacks, including its baseless attack on the reliability of the *Journal of Anesthesia & Surgery*, fail to support its relevancy argument.

C. Although Borak’s Testimony Decimates 3M’s Reliance on Jeans, the Sousa Study Provides Additional Scientific Evidence to Show that MSSA Screening Did Not Impact the DJI Rates Reported in McGovern

Finally, 3M argues that Sousa is irrelevant for two reasons. *First*, despite its claim that “controlling for just the confounders disclosed by the authors . . . eliminates the ‘association’ between Bair Hugger and DJIs” based on a slim sliver of McGovern’s data,

3M now argues that Sousa is “underpowered.” *Cf.* Dkt. 1919 at 14. 3M’s argument is not only hypocritical; it also misses the point. Statistical power has nothing to do with the fact that Sousa, unlike Jeans, distinguishes between DJI and SSI in evaluating the impact of MSSA screening. And rightly so as DJIs are caused by “exogenous,” not endogenous sources. Hence Sousa’s conclusion that there is “enough evidence that nasal screening of [MSSA] at the time of surgery is a risk factor for SSI in orthopedic surgery, [but] there is no definitive evidence regarding [DJI] specifically.” Thus, whether or not Jeans included “more than 10,000 patients,” 3M’s own expert conceded that Jeans does “suggest” a difference in DJI rates from MSSA screening given the study’s failure to distinguish between two very different injuries. Dkt. 1914 at 19 (citing Borak Dep. II at 35:21-36:14).

Second, 3M says that Jeans “included the same patient population as the McGovern study and determined that MSSA screening was associated with lower infection rates in that population.” This argument fails for the simple reason that Jeans neither included the same data nor reported on the same outcome (*i.e.*, DJI) as McGovern, as Plaintiffs have explained in prior briefing. Dkt. 1786 at 38 n.12. Moreover, 3M continues to ignore the sworn testimony of Dr. Borak, who readily conceded on cross-examination that Jeans does not suggest—much less confirm—that MSSA screening confounded McGovern. If anything, he stated, Bair Hugger may have founded Jeans. *See* Dkt. 1813-42 at 3, 6 (Borak Dep. II at 13:2–25, 36:10–14). Put simply, 3M’s own expert disclaimed the opinion that the company now attempts to ascribe to him. Instead of withdrawing its meretricious motion, 3M yet again disregards this damning evidence and asks this Court to do the same.

CONCLUSION

For the foregoing reasons, the Court should deny 3M's evidentiary challenges to the Lange, Sugai, and Sousa studies. All three of the studies should be admitted into evidence.

Respectfully submitted,

Dated: June 19, 2019

CIRESI CONLIN L.L.P.

/s/ Michael V. Ciresi

Michael V. Ciresi (MN #0016949)

Jan M. Conlin (MN #0192697)

Michael Sacchet (MN #0395817)

Ciresi Conlin LLP

225 S. 6th St., Suite 4600

Minneapolis, MN 55402

Phone: 612.361.8202

Email: MVC@CiresiConlin.com

JMC@CiresiConlin.com

MAS@ciresiconlin.com

MESHBESHER & SPENCE LTD.

/s/ Genevieve M. Zimmerman

Genevieve M. Zimmerman (MN #330292)

1616 Park Avenue South

Minneapolis, MN 55404

Phone: (612) 339-9121

Email: gzimmerman@meshbeshesher.com

LEVIN PAPANTONIO, P.A.

/s/ Ben W. Gordon, Jr.

Ben W. Gordon (FL #882836)

316 S. Baylen Street, Suite 600

Pensacola, FL 32502-5996

Phone: (850) 435-7090

Email: bgordon@levinlaw.com

Attorneys for Plaintiffs